IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

LLOYD BELL, Individually and As Executor of the Estate of BETTY WHITLEY BELL, Deceased, Plaintiff, v. AMERICAN INTERNATIONAL INDUSTRIES, et al., Defendants.	)	CASE NO. 1:17-CV-00111

NORTHWELL HEALTH, INC.'s MEMORANDUM OF LAW IN SUPPORT OF MOTION TO INTERVENE AND EXTEND PROTECTIVE ORDER

COMES NOW Northwell Health, Inc. ("Northwell"), pursuant to Local Rule 7.3, and files this Memorandum of Law in Support of its Motion to Intervene and Extend Protective Order ("Motion"). Northwell respectfully moves this Court to allow it to intervene in this matter for the sole purpose of seeking an extension of the existing protective order entered in this case on September 25, 2020 ("Protective Order"). Specifically, Northwell seeks extension of the Protective Order to preclude Defendants' counsels from questioning Plaintiff's expert witness, Jacqueline Moline, M.D. ("Dr. Moline"), regarding (1) whether or not Betty Whitley Bell ("Plaintiff") was a subject of Dr. Moline's peer-reviewed publication entitled, "Mesothelioma Associated with the Use of Cosmetic Talc" ("Article"); (2) the specific documentation and other information Dr. Moline reviewed and analyzed related to Plaintiff within the context of the Article; and (3) any conclusions Dr. Moline may have drawn as to the Plaintiff within the context of the Article. Plainly stated, Northwell moves this Court to prevent Defendants' counsels from questioning Dr. Moline about any linkage between Plaintiff and the Article.

As set forth in detail below, it is critical that Dr. Moline not be questioned about, and, therefore, forced to disclose, the identity of any subjects of her research study, *including* Plaintiff. Such questioning, if permitted by the Court, would be contrary to:

1. The Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46, Subpart A (or, "The Common Rule");

2. Bedrock Institutional Review Board ("IRB") standards of privacy and confidentiality covering research subjects;

3. The specific IRB approvals that Dr. Moline secured in advance of writing and publishing the Article;

4. Well-established standards and universally accepted norms in the medical research community related to research subjects and anonymity; and

5. Relevant case law affirming privacy and confidentiality requirements for research subjects.

Defendants will not be prejudiced by grant of this Motion and the extension of the Protective Order. Specifically, subject to the Court's rulings to the contrary, Defendants' counsels will still be permitted to generally question Dr. Moline as to the Article and her related methodologies, and/or about information that the Plaintiff has specifically placed in issue in the case.[1] Moreover, if the Court were to find any prejudice to Defendants by grant of this Motion, the alleged prejudice is substantially outweighed by the countervailing legal and policy considerations surrounding the privacy and confidentiality requirements/norms related to research subjects in the medical community.

As such, Northwell's Motion should be granted and the Protective Order extended to protect Dr. Moline from being questioned about the specific link between Plaintiff and the Article.

[1] Northwell takes no position on these particular issues for purposes of the Motion.

I. BACKGROUND

Dr. Moline is an employed physician at Northwell and is board-certified in internal and occupational medicine. Moline Aff. at ¶ 2 (Ex. A). In addition to other roles, Dr. Moline is the chairperson of the Department of Occupational Medicine, Epidemiology and Prevention at North Shore University Hospital, which is a part of Northwell. Id. at ¶ 3. She is also a professor of medicine at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell. Id. at ¶ 4. Dr. Moline serves on the editorial boards of several journals on industrial, occupational and environmental medicine. Id. at ¶ 5. She is a fellow of the American College of Physicians, the American College of Occupational and Environmental Medicine, and the New York Academy of Medicine. Id. at ¶ 6.

In 2019, Dr. Moline—along with Kristin Bevilacqua, MPH, Maya Alexandri, JD, and Ronald Gordon, Ph.D.—authored and published a peer-reviewed article entitled, "Mesothelioma Associated with the Use of Cosmetic Talc" ("Article"). Id. at ¶ 7. The Article was based on the authors' analysis of records associated with thirty-three individuals with malignant mesothelioma who had no known asbestos exposure other than to cosmetic talcum powder. Id. at ¶ 8. The Article's conclusion is that exposure to asbestos-contaminated talcum powders can cause mesothelioma and that clinicians should elicit a history of talcum powder usage in all patients presenting with mesothelioma. Id. at ¶ 9.

Prior to drafting the Article, Dr. Moline sought and secured approval from Northwell's Human Research Protection Program ("HRPP") through its Institutional Review Board ("IRB"). Id. at ¶ 10. Northwell's HRPP supports, facilitates, and promotes the ethical and safe conduct of research involving human subjects at Northwell. Id. at ¶ 11. The Northwell IRB is an independent research ethics review board—mandated by law and applicable regulations—and consists of

healthcare professionals, scientists, and local community members. Id. at ¶ 12. The IRB serves to protect research participants' rights and welfare before and during research studies. Id. at ¶ 14. Specifically, IRBs are intended to ensure the protection of research subjects' privacy and confidentiality rights, including—most fundamentally—their identities and protected health care information ("PHI"). Id. at ¶ 15.

In the application for approval from the Northwell IRB for the research study and publication of the Article, Dr. Moline represented that (1) she took confidentiality seriously and would take extensive measures to protect the participants' identities; (2) no patient identifiers would be included in research-related summaries; (3) all PHI included in her review and the Article would be de-identified; (4) and the PHI would be stored in Northwell's secure database. Id. at ¶ 16.

As a result of these and other representations about the research study, Norwell's IRB granted approval on March 23, 2018. Id. at ¶ 17. In so doing, the IRB approval stated that Dr. Moline's research study met the criteria outlined in 45 C.F.R. § 46.110 and 21 C.F.R. § 56.110, which relate to expedited review and are part of regulations that stringently require research subject privacy and confidentiality. Id. at ¶ 18. Indeed, the IRB approval was specifically based on the fact that Dr. Moline's research study contained adequate provisions to protect and maintain the confidentiality of data and research participants. Id. at ¶ 19. The IRB approval also specifically directed Dr. Moline that research must be conducted in accordance with, *inter alia*, 45 C.F.R. § 46 and the Health Insurance Portability and Accountability Act ("HIPAA"). Id. at ¶ 20.

Following the IRB approval in March 2018 and throughout the Article's research and publication process, Dr. Moline protected the research subjects' privacy and confidentiality. Id. at ¶ 21. Specifically, she did not disclose or otherwise reveal the research subjects' identities, as

required by Northwell's IRB and applicable laws and regulations. Id. at ¶ 22. Indeed, to date, Dr. Moline has not disclosed the identities of the research subjects in the Article. For example, when she was deposed in a separate but related case in January 2020, Dr. Moline refused to disclose Plaintiff's identity in response to questions from counsel for Defendant, American International Industries ("AII"), about the Article. Id. at ¶ 23. Dr. Moline's refusal to identify the Plaintiff's status as a research subject was based on IRB, privacy, and confidentiality standards surrounding research studies. Id. at ¶ 24.

On August 20, 2020, counsel for Defendant AII, served Northwell with a Rule 45 subpoena requesting a range of documents related to Dr. Moline including, *inter alia*, information surrounding the Article. *See* ECF No. 168-1. Counsel for AII also provided Northwell with a HIPAA Authorization signed by the executor of Plaintiff's estate. *See* ECF No. 179-6. On September 10, 2020, in response to the Rule 45 subpoena, prior outside legal counsel for Northwell disclosed to Defendant AII Plaintiff's status as one of the thirty-three research subjects in the Article. This disclosure took the form of the production of a spreadsheet listing the thirty-three research subjects, with all names redacted apart from Plaintiff's name.

As the Court is aware, the disclosure of the Plaintiff's status as part of the research study and Article on September 10, 2020 triggered substantial briefing by the parties in this matter. This briefing ultimately culminated in the Court granting Plaintiff's Motion for Emergency Protective Order as to the identities of thirty-two of the Article's research subjects, but not as to Plaintiff. Northwell files this Motion to make clear its position that it would be improper to require Dr. Moline to identify the Plaintiff's connection to the research study and Article pursuant to The Common Rule; bedrock and widely accepted IRB requirements of confidentiality and privacy; and applicable case law.

II. STANDARD OF REVIEW

A. Intervention by Northwell

It is well-settled law that under Fed. R. Civ. P. 24(b) a non-party to an action may seek to enter, expand, or challenge a protective order. Beckman Industries, Inc. v. International Ins. Co., 966 F.2d 470, 472 (9th Cir. 1992); Small v. Ramsey, No. 1:10-CV-121, 2011 WL 13311479, at *1 (N.D.W.V. June 28, 2011). In deciding to grant a motion to intervene for such purposes, the court should consider whether allowing intervention will unduly delay or prejudice the adjudication of rights of the parties to the action. Fed. R. Civ. P. 24(c).

B. Modification of Protective Order

Under Rule 26(c), for good cause shown, a court may modify a protective order in a manner that, *inter alia*, forbids inquiry into certain matters, limits the scope of discovery to certain matters, or requires confidential research not to be revealed. Fed. R. Civ. P. 26(c)(1). Accordingly, a court may limit the scope of inquiry of an oral deposition as provided in Rule 26(c). Fed. R. Civ. P. 30(d)(3). Trial courts have broad discretion under Rule 26(c) to decide "when a protective order is appropriate and what degree of protection is required." Small v. Ramsey, 280 F.R.D. 264, 269 (N.D.W.V. 2012) quoting Furlow v. U.S., 55 F.Supp.2d 360, 366 (D.Md. 1999). In evaluating whether good cause exists to grant or extend a protective order, a court balances the interest of a party in obtaining the information against the interest of the entity seeking the protective order in limiting the release of that information—i.e., the court weighs the need for the information versus the harm in it being provided. UAI Technology, Inc. v. Valutech, Inc., 122, F.R.D. 188, 191 (M.D.N.C. 1988). The burden is on the party requesting the modification of the protective order to show good cause that the modified protections are warranted. SmithKline Beecham Corp. v. Synthon Pharmaceuticals, Ltd., 210 F.R.D. 163, 166 (M.D.N.C. 2002). When a court balances a party's need for discovery against the burden imposed on the person required to disclose such

information, whether the person from whom discovery is sought is a non-party is a factor that weighs against disclosure. Am. Elec. Power Co. v. United States, 191 F.R.D. 132, 136 (S.D. Ohio 1999)

III. LEGAL ANALYSIS

Northwell seeks a narrow, yet critical, enlargement of the Protective Order to safeguard confidentiality and privacy issues central to academic research. Northwell's modification to the Protective Order would limit one line of inquiry: the identity of anonymous individuals referenced in Dr. Moline's Article, including whether Plaintiff was one of the research subjects. This modified Protective Order would be narrowly tailored such that the balance of interest analysis is straightforward. It protects vital confidentiality and privacy interests fundamental to medical research. In contrast, such lines of inquiry would be of no probative value to Defendants in this case, and thus granting Northwell the relief requested would not prejudice the Defendants.

A. Northwell Has Significant Interests in Protecting the Identify of Research Subjects in Northwell IRB-Approved Research

Dr. Moline's Article was researched and published consistent with Northwell's IRB processes, as directed by The Common Rule. The Common Rule is well-established federal policy aimed at protecting the safety, privacy, and confidentiality of research subjects. It imposes a series of requirements on institutions engaging in human subject research, which is subject to regulation by applicable federal agencies, including the U.S. Department of Health and Human Services ("HHS"). See 45 C.F.R. § 46.101. Institutions like Northwell that are engaged in human subject research are required to follow the policies and processes set forth within The Common Rule as part of the terms of the research institution's Federalwide Assurance established with the Office of Human Research Protections ("OHRP"), an office within HHS. See 45 C.F.R. § 46.103(a).

Although Dr. Moline did not have direct person-to-person contact with patients in researching the Article, her analysis of identifiable medical records in preparing her research findings qualified as human subject research for purposes of The Common Rule. See 45 C.F.R. §46.102 (defining human subject research as including research in which a researcher obtains, uses, studies, or analyzes identifiable private information, such as a medical record). Accordingly, to conform to The Common Rule policies, Northwell's IRB required Dr. Moline to submit a research proposal demonstrating, among other requirements, that there were adequate protections in place to protect the privacy of the research subjects and to maintain the confidentiality of the patient's health data. 45 C.F.R. § 46.111. As discussed, Dr. Moline did just that, representing in her IRB application that (1) she took confidentiality seriously and would take extensive measures to protect the participants' identities; (2) no patient identifiers would be included in research-related summaries; (3) all PHI included in her review and the Article would be de-identified; (4) and the PHI would be stored in Northwell's secure database. *Id.* at ¶ 16. Further, in approving Dr. Moline's research proposal through the IRB informed consent waiver, the IRB had to establish that her proposal presented "no more than minimal risk of harm" to the research subjects, including a minimal risk of harm resulting from a breach of confidentiality. 45 C.F.R. § 46.117.

The IRB review process involves a balance of risks that the subjects of that research may be harmed by unexpected or inadvertent release of their information, with the benefits that the research may provide to the public. As such, both Northwell and Dr. Moline have significant interests in protecting the anonymity of the research results. If researchers and research institutions that are non-parties to litigation are required to disclose the identity of anonymous research subjects, the result would be a chilling effect on the IRB process and the medical community, including the potential for impeding the development of life-saving medical breakthroughs. Such

disclosure requirements would require IRBs to reassess the risks and benefits associated with all research proposals in light of the newly expanded risks to research subject confidentiality that such court orders would represent. The fact that a research subject becomes a plaintiff in litigation does not ameliorate this concern, nor does it change the representations Dr. Moline made to Northwell's IRB or Northwell's IRB's obligations under The Common Rule. This is particularly true here, where Plaintiff's status as a research subject is not central to any issue in this case, and there is no evidence Plaintiff was even aware she was a research subject.

In light of these concerns common through the medical research community, courts regularly protect the confidentiality of the research process, affording special discovery protections to research scholars and their research publications. See, e.g., Cusumano v. Microsoft Corp., 162 F.3d 708 (1st Cir. 1998) (holding First Amendment considerations justify protecting academics engaged in scholarly research so as to prevent a chilling effect on the ability of researchers to gather and disseminate information); In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, 249 F.R.D. 8, 13–14 (D.Mass. 2008) (finding chilling effects would occur if the identity of anonymous peer reviewers were required to be disclosed in product liability discovery). In Cusumano, the court noted the particular First Amendment harm to the free flow of information—essential to the research process—when researchers are ordered to violate their assurances of confidentiality. Id. at 716–717. Courts have long recognized that this confidentiality is often "essential to the ability of researchers to obtain data." Andrews v. Eli Lilly & Co., Inc., 97 F.R.D. 494, 499 (N.D.Ill. 1983), citing Richards of Rockford, Inc. v. Pacific Gas & Electric Co., 71 F.R.D. 388, 390 (N.D.Cal.1976); Lampshire v. Proctor & Gamble Co., 94 F.R.D. 58 (N.D.Ga.1982). Protecting the free flow of information to research partners thus not only benefits

Northwell, but also serves a compelling societal interest that is jeopardized when confidentiality is breached. Id.

B. The Narrow Extension of the Protective Order Sought by Northwell Will Not Prejudice AII

Balanced against Northwell's interests, the Court must consider Defendants' need for the information sought. Here, the Defendants make a meagre showing, as Plaintiff's participation, or not, in a research study is a picayune issue not central to any question or defense in this litigation. The modification of the Protected Order that Northwell seeks would not prevent Defendants from obtaining any medical records or other relevant history regarding Plaintiff. Nor is Northwell seeking to limit Defendants from attempting to impeach Dr. Moline. This modification will not limit Defendants' counsels from questioning Dr. Moline about the background, methods, or analysis conducted by Dr. Moline in preparing the Article. Instead, Northwell only seeks to protect the identities of *all* of the subjects of Dr. Moline's research. Accordingly, the requested extension of the Protective Order will not prevent Defendants from impeaching Dr. Moline or having a complete picture of the Plaintiff's medical history.

In prior briefing by Defendant AII in response to Plaintiff's September 15, 2020 Emergency Motion for Protective Order, Defendant AII argued that it had an interest in knowing whether Plaintiff was a research subject, alleging her status as a research subject could call into question assertions made about Plaintiff's prior exposure to asbestos. ECF No. 197, p. 11. However, whether or not Plaintiff was a subject of a research study simply has no bearing on whether or not she had prior exposure to asbestos. To the extent that Dr. Moline has facts or information relevant to inquiries about Plaintiff's prior exposure to asbestos, this modified Protective Order would not limit that line of questioning. Thus, the narrow limitation sought by Northwell will not prejudice Defendabt AII.

In addition, granting Northwell's Motion to Intervene will not result in any undue or prejudicial delay to any of the Defendants. Dr. Moline is available for deposition and, as noted, this modification of the Protective Order will merely limit one line of questioning by Defendants' counsels.

IV. CONCLUSION

For the foregoing reasons, Northwell respectfully requests that the Court grant its Motion, extends the Protective Order as Northwell requests, and precludes Defendants' counsels from questioning Dr. Moline about any linkage between Plaintiff and the Article.

This the 23rd day of December, 2020.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 23, 2020, the foregoing Memorandum of Law was filed via ECF filing, which will serve all counsel of record in the above-referenced matter.

This the 23rd day of December, 2020.

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/s/ John H. Lawrence
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